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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/911,563	07/24/2001	Thomas P. Osypka	695716.0016 (OSCO-114)	6118

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EXAMINER

MAYNARD, JENNIFER J

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/911,563

Applicant(s)

OSYPKA ET AL.

Examiner

Jennifer J Maynard

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 17-32 is/are pending in the application.
- 4a) Of the above claim(s) 13-15 and 17-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 25-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

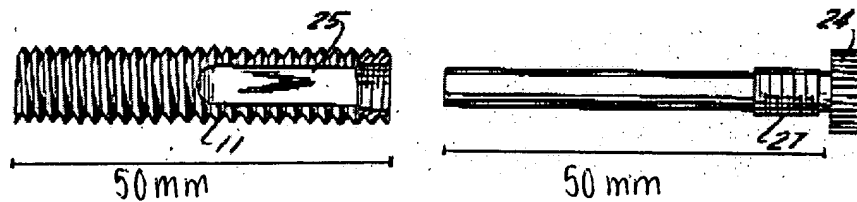
Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Zeman (US 3,540,451 A).

Zeman discloses a drainage cannula with threaded sealing pin comprising an access port defining an elongated tubular body (11) of predetermined length with a central lumen (25) having opposed proximal and distal end portions (the proximal end is interpreted as the portion adjacent to overprotective button (22), while the distal end is labeled (11a)) and an inner diameter, the distal end portion defining a flat annular distal end surface (see Figure 1 or 2); and an elongated cylindrical plug (24) dimensioned and configured for insertion into the central lumen of the cannula and ready removal therefrom, the plug body having a length that is substantially equal to the cannula, a flat circular distal end surface, see Figure 2, and an outer diameter that is substantially equal to the inner diameter of the lumen so as to prevent flow between the outer diameter of the plug and the inner diameter of the lumen of the cannula when the plug is engaged therein and the flat annular distal end surface of the access port is coplanar with the flat circular distal end surface of the plug body (see Figures 1 & 2); and a locking mechanism (27) associated with the proximal end of the elongated cylindrical plug body adjacent

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a handle portion (24) thereof for releasably coupling the plug body to the cannula, see Column 4, lines 8-10; Column 4, lines 26-28, and Figures 1 & 2.

** Note that the Figures do not show the sealing pin/plug inserted into the cannula/port, however the Examiner measured the lengths of the pin/plug and the cannula/port, as depicted in Figure 2, and discovered that the lengths are equal and thus upon insertion would yield a coplanar surface, see below for details.



Claims 1, 2, 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Zimmerman (US 4,318,401 A).

Zimmerman discloses a vascular access portal comprising a vascular access port (10) defining an elongated tubular body (14) of predetermined length with a central lumen (20) having opposed proximal and distal end portions (12, 30, respectively) and an inner diameter, the distal end portion adapted and configured for introduction into a blood vessel and defining a flat annular distal end surface (30, see Figure 2); and an elongated cylindrical plug (22, 34) dimensioned and configured for insertion into the central lumen of the vascular access port and ready removal therefrom to permit access to the blood vessel, the plug body having a length that is substantially equal to the vascular access port, a flat circular distal end surface (38, 40) and an outer diameter that is substantially equal to the inner diameter of the lumen so as to prevent blood flow between the outer diameter of the plug and the inner diameter of the lumen of the vascular access port when the plug is engaged therein and the flat annular distal end surface of

the access port is coplanar with the flat circular distal end surface of the plug body (see Figure 2); see Column 1, lines 63-68; Column 3, lines 3-5; Column 3, lines 14-20; and Column 3, lines 21-27.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-8, 11, 12 and 25-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zimmerman (US 4,318,401 A) in view of Zemen (US 3,540,451 A).

Zimmerman disclose the invention as claimed with the exception of a locking mechanism, in the form of threads, associated with the proximal end of the elongated cylindrical plug body for coupling the plug body to the vascular access port; and wherein the plug body, handle portion and locking mechanism are formed monolithically.

Zemen discloses a cannula porting device comprising an access port defining an elongated tubular body (11) of predetermined length with a central lumen (25) having opposed proximal and distal end portions (the proximal end is interpreted as the portion adjacent to overprotective button (22), while the distal end is labeled (11a)) and an inner diameter, the distal end portion defining a flat annular distal end surface (see Figure 1 or 2); and an elongated cylindrical plug (24) dimensioned and configured for insertion into the central lumen of the cannula and ready removal therefrom, the plug body having a length that is substantially equal to

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the cannula, a flat circular distal end surface, see Figure 2, and an outer diameter that is substantially equal to the inner diameter of the lumen so as to prevent flow between the outer diameter of the plug and the inner diameter of the lumen of the cannula when the plug is engaged therein and the flat annular distal end surface of the access port is coplanar with the flat circular distal end surface of the plug body (see Figures 1 & 2); and a locking mechanism (27) associated with the proximal end of the elongated cylindrical plug body adjacent a handle portion (24) thereof for releasably coupling the plug body to the cannula, see Column 4, lines 8-10; Column 4, lines 26-28, and Figures 1 & 2.

It would have been obvious to one having ordinary skill in the art to have provided Zimmerman's vascular access portal with a locking mechanism, in the form of threads, associated with the proximal end of the elongated cylindrical plug body for coupling the plug body to the vascular access port, so as to ensure that a hermetic seal remains intact during periods of non-use, thus avoiding contamination of the portal and inhibiting inadvertent removal of the plug.

Claims 1-3, 5, 6, 8-12, 25, 26 and 28-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hubert (US 3,572,333 A) in view of Zimmerman (US 4,318,401 A).

Hubert discloses an apparatus for facilitating vascular access comprising a vascular access port (15) defining an elongated tubular body (16) of predetermined length with a central lumen bounded by a continuous, uninterrupted outer wall, the tubular body having opposed proximal and distal end portions and an inner diameter, the distal end portion adapted and configured for introduction into a blood vessel; and an elongated cylindrical plug (10, 12)

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dimensioned and configured for insertion into the central lumen of the vascular access port and ready removal therefrom to permit access to the blood vessel, the plug body having a length that is substantially equal to the vascular access port and an outer diameter that is substantially equal to the inner diameter of the lumen so as to prevent blood flow between the outer diameter of the plug and the inner diameter of the lumen of the access port when the plug is engaged therein; and a locking mechanism (27, 29) associated with the proximal end of the elongated cylindrical plug body adjacent a handle portion (20) thereof for releasably coupling the plug body to the vascular access port, see Column 1, line 69 through Column 2, line 5; Column 3, lines 13-24 and Figures 1 and 2.

Hubert fails to disclose the access port having an elongated tubular body defining a flat annular distal end surface, and a plug having a flat circular distal end surface, so the flat annular end surface of the access port is coplanar with the flat circular distal end surface of the plug when the plug is inserted into the access port.

Zimmerman discloses a vascular access portal comprising a vascular access port (10) defining an elongated tubular body (14) of predetermined length with a central lumen (20) having opposed proximal and distal end portions (12, 30, respectively) and an inner diameter, the distal end portion adapted and configured for introduction into a blood vessel and defining a flat annular distal end surface (30, see Figure 2); and an elongated cylindrical plug (22, 34) dimensioned and configured for insertion into the central lumen of the vascular access port and ready removal therefrom to permit access to the blood vessel, the plug body having a length that is substantially equal to the vascular access port, a flat circular distal end surface (38, 40) and an outer diameter that is substantially equal to the inner diameter of the lumen so as to prevent

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blood flow between the outer diameter of the plug and the inner diameter of the lumen of the vascular access port when the plug is engaged therein and the flat annular distal end surface of the access port is coplanar with the flat circular distal end surface of the plug body (see Figure 2); see Column 1, lines 63-68; Column 3, lines 3-5; Column 3, lines 14-20; and Column 3, lines 21-27.

It would have been obvious to one having ordinary skill in to have provided Hubert's vascular access port with an elongated tubular body having a flat annular distal end surface and plug with a flat circular distal end, so as that the flat annular end surface of the access port is coplanar with the flat circular distal end surface of the plug when the plug is inserted into the access port thus avoiding dead space which could lead to blood clotting therein and eventual thrombosis of the artery or vein.

Claims 4, 7 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hubert (US 3,572,333 A) in view of Zimmerman (US 4,318,401 A).

Hubert in view of Zimmerman discloses Applicant's claimed apparatus for facilitating vascular access with the exception of the plug body, handle portion and locking mechanism being formed monolithically.

It would have been a matter of obvious design/engineering choice to have formed Hubert's elongated cylindrical plug body, handle portion and locking mechanism monolithically as no criticality has been provided in the specification, nor has it been identified as solving any particular problem in the prior art, and the Examiner contends that the prior art device whose plug body (12), handle portion (20) and locking mechanism (27, 29) are separately formed but

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permanently joined together, see Column 2, lines 13-15, would perform equally as well as if they were monolithically formed and as such would constitute an obvious design choice. In re Larson, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965).

Response to Arguments

Applicant's arguments with respect to claims 1-12 and 25-32 have been considered but are moot in view of the new ground(s) of rejection.

In response to Applicant's arguments with respect to the 35 U.S.C. 103(a) rejection of Claims 4, 7 and 27 based on Hubert (US 3,572,333 A) in view of Zimmerman (US 4,318,401 A), the Examiner has failed to locate Hubert's disclosure teaching away from monolithic construction...rather Hubert discloses a manufacturing process unique to the technology at the time that Hubert's device was invented, however technology has not stagnated but advanced since that time. Therefore, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to have relied upon injection molding processes, or the like, to make Hubert's device thus rendering an assembly step unnecessary if so desired by the manufacturer thereby rendering Applicant's claimed invention obvious. Applicant has failed to address the fact that no criticality was provided in Applicant's specification at the time the invention was made to support the patentability of monolithic construction. Therefore the Examiner has found Applicant's arguments unpersuasive.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

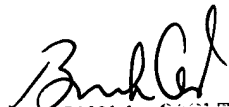
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer J Maynard whose telephone number is 703.305.1356. The examiner can normally be reached on Mondays-Fridays 9:30 AM-5:30 PM; 1st Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703.308.3552. The fax phone numbers for the organization where this application or proceeding is assigned are 703.872.9302 for regular communications and 703.872.9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.0858.

J Maynard
January 25, 2004


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